

REMARKS

A. Status of the Claims

By the present amendment, claims 1, 18 and 35 have been amended to more particularly define the Applicants' invention and to claim it with greater accuracy and specificity. Claims 2, 3, 6, 9, 10, 12-14, 19, 20, 23, 27, 28, 32-34, 36, 37, 40, 44, 45 and 49-59 were canceled previously. New claims 60-86 have been added.

The claims amendments and new claims are supported by the specification and the original claims. No new matter has been added. More specifically, each of new claims 60, 69 and 78 recites the following limitation: "wherein the microbial organism of interest is selected from the group consisting of a cell, a bacterium, a virus, a yeast, a fungus, another unicellular organism and a multicellular organism." This limitation is supported by the originally filed application. See, paragraph [0082] of the application as published (US2002-0142326).

After the present amendment has been entered, claims 1, 4, 5, 7, 8, 11, 15-18, 21, 22, 24-26, 29-31, 35, 38, 39, 41-43, 46-48 and 60-86 will remain pending and will remain under consideration.

B. Objections to Drawings

The Examiner has advised that some figures are of the quality which is below the accepted standard and required that replacement drawing be submitted (see, item 2 on page 2 of the Office Action). The Applicants would like to thank the Examiner for his suggestions and will provide the replacement figures in due course.

C. Objections to the Specification

The Examiner has stated that certain incorporations by reference set forth in the application are improper (see, item 4 on page 4 of the Office Action). There were

previously a number of arguments and discussions on this point, and the Applicants continue to believe that the Examiner is mistaken, for the reasons of the record.

However, the Applicants don't quite see the Examiner's point. The Examiner has not stated that the specification is defective and requires amendments or replacement. The Applicants respectfully request clarification and explanation for which particular purpose has this objection been made. As is clear from the discussion that follows, the Applicants do not rely on the incorporated references for descriptive support of particular limitations in the claims.

Therefore, this objection appears to be irrelevant. Reconsideration and withdrawal of the objection are requested.

B. Rejections under 35 U.S.C. §112, First Paragraph (Written Description)

Claims 1, 4, 5, 7, 8, 11, 15-18, 21, 22, 24-26, 29-31, 35, 38, 39, 41-43 and 46-48 stand rejected under 35 U.S.C. §112, first paragraph, as allegedly failing to comply with the written description requirement (item 7 on page 7 of the Office Action).

As a preliminary matter, the Applicants respectfully point out that a similar rejection was made by the Examiner in the Office Action mailed February 21, 2008 with respect to the communication from the Applicants dated March 13, 2006. However, after the Applicants filed another amendment on February 17, 2009, the written description rejection was withdrawn since in the next Office Action mailed April 1, 2009 since this rejection no longer appeared. Now, this rejection has appeared again, after the Examiner has examined the claims and amendments filed together with the Request for Continued Examination (RCE) filed May 3, 2010, even though the claims filed with the RCE were essentially the same as the claims filed with the February 17, 2009 amendment, after which the written description rejection no longer appeared.

With all due respect, the Applicants respectfully submit that the Examiner seems to be conducting examination in a piecemeal fashion, making a rejection, withdrawing it, and

then making the same rejection again. Such a practice is improper. See, MPEP Section 707.07(g) directing the examining corps to avoid piecemeal examination and requiring that if there are valid rejections, they must be made on all valid grounds available.

Turning now to the merits of the written description rejections, the Applicants respectfully disagree and traverse these rejections on the grounds that the Examiner has not met the burden of demonstrating that the claims are directed to the subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that at the time of invention had possession of the claimed invention.

The burden of showing the insufficiency of written description is squarely the Examiner's, as required by *In re Wertheim*, 541 F.2d 257, 263, 191 USPQ 90, 97 (CCPA 1 976). MPEP specifically states that a strong presumption of adequacy of written description exists and directs that § 112, paragraph 1 rejections of an original claim should be rare. MPEP §§ 2163(I)(A) and 2163(II)(A). It is respectfully submitted that in this case the Examiner has not met the burden of demonstrating an alleged lack of written description.

The legal standard for determining the adequacy of written description is clear and well established. The description is adequate if "the disclosure of the application relied upon reasonably conveys to the artisan that the inventor had possession at [the time of filing] of the later claimed subject matter." *Wang Labs Inc. v. Toshiba Corp.*, 993 F.2d 858, 26 USPQ2d 1767. In other words, the question of the lack of adequate written description does not arise unless "one skilled in the art [would not be able] to immediately envisage the product claimed..." *Fujikawa v. Wattanasin*, 93 F.3d 1559, 39 USPQ2d 1895. It is submitted that applying these broad principles to the pending claims, it can be concluded that the written description in this application adequately supports the claims.

The Examiner has stated that the instant claims encompass "a generic claim" where "the microbe of interest is without limit." See, item 12 on page 9 of the Office

Action. Furthermore, the Examiner has stated that the Applicants had provided “forward-looking statements” as to the future plans to explain why desired selectivity was not achieved. See, item 15 on page 10 of the Office Action, from which the Examiner has inferred that at the time of filing the Applicants were not yet in possession of all the means necessary to practice the claimed methods. Based on these observations, the Examiner concluded that the Applicants were not in possession of the claimed invention at the time of filing the application, thus failing to satisfy the written description requirement. See, item 18 bridging pages 11 and 12 of the Office Action. The Applicants respectfully submit that this analysis is not quite correct.

The instant claims are fully supported by the original specification, as filed, and every limitation is fully disclosed throughout the specification. Indeed, the “microbial organism of interest” is described, e.g., in paragraphs [0082], [0083], etc. of the application as published (US2002-0142326). The “binding partner” has now been replaced in the claims with “antibody” and both are described, e.g., in paragraphs [0033], [0093], [0103], etc. (for “binding partner”) or in paragraphs [0024], [0025], [0044], etc. (for “antibody”) of the application as published (US2002-0142326). The “peptide nucleic acid” is described, e.g., in paragraphs [0006], [0018], [0027], etc., as published (US2002-0142326). The “detectable molecular probe” is described, e.g., in paragraphs [0023], [0026], [0137], etc. of the application as published (US2002-0142326).

As to the “forward-looking statement” concerning selectivity, the Examiner has misinterpreted the meaning of it. The Applicants simply outlined their future research plans. There is nothing in this statement that can negate the result already achieved. Just because more can be done in the future, does not mean that what has already been done is insufficient or somehow vitiates the possession of the methods that are described and claimed.

It is, therefore, clear, that each element of the claimed methods is plainly disclosed and described within the application as filed. Accordingly, it is the Applicants' position that the Examiner's view that some elements are not so described is definitely erroneous

Turning now to the Examiner's position that the Applicants are not entitled to the entire genus (e.g., the genus of microbial organisms), the case law is clear that when a genus is involved, all that is required is that the specification must disclose a reasonable number of particular species encompassed by the genus. *In re Ruschig*, 154 USPQ 118 (CCPA 1967). Nothing more is required, and it has never been a rule that an applicant is required to describe every or even many species constituting the genus in question. To the contrary, there exists case law holding that in some situations, the disclosure of even just one or two particular species could suffice. This requirement is satisfied because the instant application discloses several specific microbial organisms and how the claimed methods are to be practiced with respect to such organisms. See, e.g., the description with respect to *Salmonella*, *E. coli* and *Pseudomonas aeruginosa* in paragraph [0132] of the application as published (US2002-0142326). See also Example 1 in paragraph [0152] of the application as published (US2002-0142326) with respect to *Salmonella* and *Listeria*.

In addition, the Applicants have added new claims 60-86 directed which are narrower than the originally filed claims in that they contain the following limitation: "wherein the microbial organism of interest is selected from the group consisting of a cell, a bacterium, a virus, a yeast, a fungus, another unicellular organism and a multicellular organism." It is submitted that the specification provides even better written description for such more limited genus.

In view of the foregoing, it is submitted that claims 1, 4, 5, 7, 8, 11, 15-18, 21, 22, 24-26, 29-31, 35, 38, 39, 41-43 and 46-48 satisfy the written description requirement and the rejection does not apply. Accordingly, reconsideration and withdrawal of the rejection of claims under 35 U.S.C. § 112, first paragraph is respectfully requested.

In Re Application Of:
Coull et al.
Application No.: 09/966,658
Filed: November 29, 2001
Page 21

PATENT
Attorney Docket No.: BP-0002-1 US

CONCLUSION

Favorable action on all claims is respectfully requested. In the event any matters remain to be resolved, the Examiner is requested to contact the undersigned at the telephone number given below so that a prompt disposition of this application can be achieved.

No fee is deemed necessary with the filing of this response. However, if any fee is due, the Commissioner is hereby authorized to charge any fees required in conjunction with the instant paper to Deposit Account No. 50-3994 (**Order No. BP-0002-1 US**)

Respectfully submitted,

Date: August 20, 2010

/Victor Repkin/
Victor Repkin
Attorney for Applicants
Reg. No. 45,039

LIFE TECHNOLOGIES
5781 Van Allen Way
Carlsbad, CA 92008
Telephone: (619) 871-5161
Facsimile: (619) 688-3002
CUSTOMER NUMBER NO. 22896